

### **DETAILED ACTION**

This action is in response to amendments/arguments filed 2/5/2008. Currently, claims 12-22 are pending in the instant application.

#### ***Response to Arguments***

Applicant's arguments filed 2/5/2008 have been fully considered but they are not persuasive. Applicant argues the Caspers device teaches away from the claimed invention. However, Applicant provides no evidence or citation in the reference showing the Caspers' reference teaches away from the claimed invention. Further Applicant argues, Caspers fails to teach placing a spaces around the perimeter of the limb prior to applying the cast forming gauze. However, Caspers teaches the application of a casting sock (i.e. spacer) prior to the application of plaster of paris and gauze, which would be cast forming gauze. Applicant argues none of the prior art of record teaches cutting the cast proximate the spacer. However, it is well known in the art of casting that the edges of the cast are cut down to not over lap the spacer and present a sharp edge that could cut the user.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 -15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspers (US Patent 5,571,208) in view of Kania (US Patent 5,830,237), Vanden (US Patent Application Publication 2003/0114783), and Schon et al. (US Patent 6,368,357). Caspers discloses a method of dressing a post-operative residual limb (12) comprising applying a liner (90) on a residual limb (12), covering a the liner (90) with a protective covering (50), placing a spacer (42) around the residual limb (12) prior to applying the cast forming gauze (54); wherein the spacer is remove prior to using the device. It is well known in the art that the plaster of Paris used is gauze with a material that hardens after water is applied. The soft tissue or residual muscle tissue is shaped before the gauze solidifies (col. 6, lines 21-37). It would be obvious to one of ordinary skill in the art at the time of the invention to cut the cast proximate the spacer in order for the cast to fit the use without having sharp edges, this is well known in the art. Caspers fails to disclose the method including a liner that is a thermo plastic gel, the step of placing a distal pad on a distal end of the residual limb above the liner, cutting the cast along its periphery to permit removal, and securing the cast with one or more securing mechanism.

Kania teaches a removable post operative limb dressing comprising a thermoplastic gel liner (cushion liner, Figure 7A) and a protective covering over the liner (fabric liner, column 6, lines 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the Caspers' liner with the thermo plastic gel liner as taught by Kania, because it is easy to manipulate and provides the user with more comfort.

Vanden teaches a method of making a hinged orthopedic device (1) comprising cutting a finished device lengthwise and hinging the device (par. 0005) forming two portions (fig. 3A), and a securing mechanism (7, 8, 9). The device cut should be a moldable material, such as plaster of paris. The device is for the arm, however it is analogous to all amputated limbs. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Casper/Kania to include the step of cutting the device to permit removal, hinging it, and securing it with a strap, as taught by Vanden, because it would allow easy application and removal of the device.

Schon teaches a therapeutic device (200) for amputees comprising a distal pad (210) at the distal end of the residual limb. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify device of caspers/Kania/Vanden to have a distal pad, as taught by Schon, in order to provide the user with more comfort and support in that weight bearing area. It would also be obvious to one of ordinary skill in the art to cut the device proximate the distal pad when cutting its periphery.

Claims 16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspers (US Patent 5,571,208) in view of Kania (US Patent 5,830,237) and Vanden (US Patent Application Publication 2003/0114783). Caspers discloses a method of dressing a post-operative residual limb (12) comprising applying a liner (90) on a residual limb (12), covering a the liner (90) with a protective covering (50), placing a spacer (42) around the residual limb (12) prior to applying the cast forming gauze (54); wherein the spacer is remove prior to using the device. It is well known in the art that the plaster of Paris used is gauze with a material that hardens after water is applied. The soft tissue or residual muscle tissue is shaped before the gauze solidifies (col. 6, lines 21-37). It would be obvious to one of ordinary skill in the art at the time of the invention to cut the cast proximate the spacer in order for the cast to fit the use without having sharp edges, this is well known in the art. Caspers fails to disclose the liner is thermo plastic gel, cutting the cast along its periphery to permit removal, and securing the cast with one or more securing mechanism.

Kania teaches a removable post operative limb dressing comprising a thermoplastic gel liner (cushion liner, Figure 7A) and a protective covering over the liner (fabric liner, column 6, lines 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the Caspers liner with the thermo plastic gel liner as taught by Kania, because it is easy to manipulate and provides the user with more comfort.

Vanden teaches a method of making a hinged orthopedic device (1) comprising cutting a finished device lengthwise and hinging the device (par. 0005) forming two

portions (fig. 3A), and a securing mechanism (7, 8, 9). The device cut should be a moldable material, such as plaster of paris. The device is for the arm, however it is analogous to all amputated limbs. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Caspers/Kania to include the step of cutting the device to permit removal, hinging it, and securing it with a strap, as taught by Vanden, because it would allow easy application and removal of the device.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caspers/Kania/Vanden as applied to claim 16 above, and further in view of Schon et al. (US Patent 6,368,357). Caspers/Kania/Vanden fails to disclose placing a pad proximate a joint and cutting the cast proximate the pad. However, Schon teaches a therapeutic device (200) for amputees comprising a distal pad (210) at the distal end of the residual limb. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Caspers/Kania/Vanden device to have a distal pad, as taught by Schon, in order to provide the user with more comfort and support in that weight bearing area. It would also be obvious to one of ordinary skill in the art to cut the device proximate the distal pad when cutting its periphery.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/  
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772